DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2855h

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

August 5, 1999

Our Reference: 2953809

Stephen J. Rasmussen, Owner
Roundman's Smoke House & Wholesale Meats
412 North Main Street
Fort Bragg, California 95437

WARNING LETTER

Dear Mr. Rasmussen:

On January 25, 27, and 28, 1999, Investigators Darla Bracy and Barbara Arrais of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection detected deviations which constitute violations of the Federal Food, Drug, and Cosmetic Act, and related regulations for seafood processing and good manufacturing practices.

Specifically, these deviations were:

(1) Failure to verify that the critical limits and the monitoring procedures in the HACCP plans for vacuum packaged hot smoked salmon and vacuum packaged hot smoked albacore tuna are sufficient to control the food safety hazard of *Clostridium botulinum* toxin formation, as required by 21 CFR 123.8(a); and

(2) Failure to list adequate critical limits, as defined in 21 CFR 123.3(c), and monitoring procedures for the control of *C. botulinum* toxin formation in the HACCP plans for vacuum packaged hot smoked salmon and vacuum packaged hot smoked albacore tuna, as required by 21 CFR 123.6(b), 21 CFR 123.6(c)(3) and (4), and 21 CFR 123.16.

In conjunction with the inspection, samples of smoked salmon, represented by FDA collection report number 41140, and smoked albacore tuna, represented by FDA collection report number 41141, were collected and analyzed by FDA. Results of the analyses showed that seven of the ten subsamples of smoked salmon have water phase salt below 3.5 percent. Each of the ten subsamples was found to contain less than 100 parts per million (ppm) of nitrite. The FDA laboratory also found that five of the ten subsamples of smoked albacore tuna have water phase salt levels below 3.5 percent with all ten sub-samples containing nitrite at less than 100 ppm.

Based on scientific studies, FDA recommends that the water phase salt in the loin muscle be 3.5 percent or higher, or, where permitted (as in the case of salmon, but not tuna), the combination of 3.0 percent water phase salt in the loin muscle, and not less than 100 ppm nitrite. FDA is not aware of scientific studies supporting that the water phase salt and nitrite levels found in your products are adequate for preventing *C. botulinum* toxin formation in a refrigerated, vacuum packaged, smoked salmon and tuna.

The test results obtained by the FDA laboratory on the samples of smoked salmon and smoked tuna reveal that your firm does not have adequate controls to prevent *C. botulinum* toxin formation in a vacuum packaged smoked fish or smoke-flavored fish. Smoked salmon and smoked albacore analyzed for your firm by [redacted] in August and September 1998, were also significantly low in water phase salt. These data demonstrate that your firm has not adequately established a process that will consistently provide a finished product with the desired water phase salt and the appropriate nitrite levels.

You may wish to review Fish & Fisheries Products Hazards & Controls Guide: Second Edition, Chapter 13 for information about appropriate controls for *C. Botulinum* toxin formation and make the necessary changes.

Vacuum packaged, hot smoked salmon and hot smoked albacore tuna processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act in that they were prepared, packed, or held under insanitary conditions

whereby they may be rendered injurious to health. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k).

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have instituted to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please include in your response documentation to show that the recipe utilized in brining was the result of a scientific study that would consistently result in a finished product with the desired water phase salt and the appropriate nitrite level. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,

Patricia C Ziobro

Patricia C. Ziobro
Director
San Francisco District

cc: Mr. and Mrs. Steve Scudder, Co-owners